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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/530,664	04/06/2005	Naoki Izumimoto	Tan-05-1079	7651

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IP GROUP OF DLA PIPER RUDNICK GRAY CARY US LLP
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EXAMINER

AULAKH, CHARANJIT

ART UNIT	PAPER NUMBER
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1625

DATE MAILED: 06/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/530,664	Applicant(s) IZUMIMOTO ET AL.	
	Examiner Charanjit S. Aulakh	Art Unit 1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9 and 11-23 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-9 and 11-23 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>06/01/2006</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

1. According to a preliminary amendment filed on April 6, 2005, the applicants have canceled claim 10, amended claims 1-9, 11, 19 and 20 and furthermore, have added new claims 21-23.
2. Claims 1-9 and 11-23 are now pending in the application.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1-9 and 21-23 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The following eight different factors (see *Ex parte Foreman*, 230 USPQ at 547; *Wands, In re*, 858.F. 2d 731, 8 USPQ 2d 1400, Fed. Cir. 1988) must be considered in order for the specification to be enabling for what is being claimed:

Quantity of experimentation necessary, the amount of direction or guidance provided, presence or absence of working examples, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability and the breadth of claims. In the instant case, the specification is not enabling based on at least four of the above mentioned eight different factors such as quantity of experimentation

necessary; the amount of direction or guidance provided, presence of working examples, the state of the prior art, unpredictability and the breadth of claims.

The specification mentions on page 1 that at present, anticholinergic drugs are used for treating urinary frequency or urinary incontinence although no prior art reference was cited to support this. The specification demonstrates inhibitory effect of instant compounds against rhythmic bladder contractions in female SD rats as shown in example 112, pages 197-202. However, there is no teaching or guidance present in the instant specification or prior art references provided to show that inhibition of rhythmic bladder contractions in female SD rats is well known animal model in the prior art for evaluating efficacy of new compounds for treating urinary incontinence or urinary frequency. There is no teaching in the instant specification or prior art regarding well known utility of structurally closely related compounds for treating urinary incontinence or urinary frequency. The applicants mention on page 1 that at present, anticholinergic drugs are used for treating urinary incontinence or urinary frequency. However, the instant compounds are morphine derivatives which are well known to have analgesic property based on their agonist activity at opiate mu receptors. There is no teaching in the specification regarding any mechanism of action of instant compounds for the recited utility of treating or preventing urinary incontinence or urinary frequency. It is well known in the prior art that there are numerous mechanisms involved in the etiology of any known disease condition. Therefore, correcting one of these mechanisms will not prevent (completely cure) that disease condition. The instant compounds of formula (I) encompasses several hundreds of thousands of compounds based on the values of

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variables R1-R4, R9-R11, Y, Z, X and k and therefore, in absence of such teachings and guidance, it would require undue experimentation to demonstrate the efficacy of instant compounds in known animal models of urinary incontinence or urinary frequency and hence for treating but not preventing these disease conditions.

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 1-9 and 11-23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In independent claim 1, for the values of variable R4, the applicants mention on page 2, last line as well as on page 3, line 3 that two R4s bound to the same sulfur atom represent ----. However, according to definition of variable X, it can not represent S. The value of variable X is defined as C2-C7 carbon chain wherein one or more carbon atoms may be substituted by nitrogen, oxygen or sulfur atom. There is no mention of replacing carbon atom with sulfur, nitrogen or oxygen atom.

In independent claims 1 and 11, the text under formulae (I) and (II) starts with a bracket – (--. However, this same bracket is used at numerous occasions in the claim and therefore, it is not clear where the initial sentence ends with this bracket. It is very confusing. The applicants should either delete this bracket or use different type of brackets to differentiate various sentences.

In claims 1-8, the term ---therapeutic or prophylactic agent --- is vague and indefinite since it is not clear whether the claims are directed to compounds of formula (I) or

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therapeutic agent for treating any disease condition or treating only urinary incontinence or urinary frequency. If it is directed to method of treatment, then the method steps are missing in the claims.

Claim 9 is directed to treating urinary frequency or urinary incontinence using compounds of claim 1. However, claim 1 is directed to a therapeutic agent for urinary frequency and urinary incontinence and therefore, appears redundant.

In independent claim 11, the values of various variables are not defined. The applicants mention that variables represent same meaning as described above. However, it is not clear where these variables are described?

In claims 22 and 23, the term ---preventing--- is indefinite since the degree of prevention (20%, 40%, 60%, 80% or 100%) is not defined and furthermore, it is not clear how this prevention is being assessed?

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1, 4-8 and 19 are rejected under 35 U.S.C. 102(b) as being anticipated by Iwai (JP 41-18824 and JP 41-18826, cited in the application on page 2).

Iwai discloses morphinan derivatives having a nitrogen-containing heterocyclic group and their use as analgesics and antitussives as admitted by the applicants on page 2, lines 1-2. These compounds anticipate the instant claims when nitrogen-containing heterocycle represents pyrrolidine or piperidine since the instant claims are directed to a

therapeutic agent and not to a method of treating urinary incontinence or urinary frequency.

8. Claims 1, 4-8 and 19 are rejected under 35 U.S.C. 102(b) as being anticipated by Brown (U.S. Patent 3,318,885).

Brown discloses morphinan derivatives having a nitrogen-containing heterocyclic group and their use as analgesics (see col. 3, lines 48-50). The compounds disclosed in examples 1-13 (see columns 4-6) by Brown anticipate the instant claims when nitrogen-containing heterocycle represents pyrrolidine, piperidine or morpholine in the instant compounds of formula (I) since the instant claims are directed to a therapeutic agent and not to a method of treating urinary incontinence or urinary frequency.

9. Claims 1 and 3-5 are rejected under 35 U.S.C. 102(b) as being anticipated by Simon (Tetrahedron).

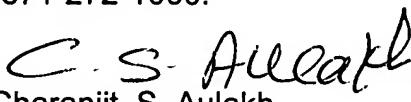
Simon discloses morphinan derivatives having a nitrogen-containing heterocyclic group. The compounds 8a-h, 9a-h, 10a-d and 11a-d (see page 9760 as well as table 1 on pages 9761-9762) disclosed by Simon anticipate the instant claims when both Y and Z represent $-C(=O)$ in the instant compounds of formula (I) since the instant claims are directed to a therapeutic agent and not to a method of treating urinary incontinence or urinary frequency.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charanjit S. Aulakh whose telephone number is (571)272-0678. The examiner can normally be reached on Monday through Friday, 8:30 A.M. to 5:00 P.M.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thomas McKenzie can be reached on (571)272-0670. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


Charanjit S. Aulakh
Primary Examiner
Art Unit 1625